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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,766

02/27/2006

Daphne Atlas

29287

9326

67801

7590

08/28/2009

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EXAMINER

FINN, MEGHAN R

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

08/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,766	Applicant(s) ATLAS ET AL.	
	Examiner MEGHAN FINN	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/20/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 22, 2009 has been entered. Claims 3-6, 8-9, and 11-19 were canceled and no claims were added by applicant. Claim 10 was amended such that it now reads upon elected subject matter and is not withdrawn, thus claims 1-2, 7, and 10 are pending.

Applicants' arguments, filed June 22, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

Applicant submitted an information disclosure statement (IDS) on August 20, 2009. The previous office action mailed January 22, 2009 was cited but marked not considered because it was already of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 7, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atlas et al. (WO 98/29375) in view of Passi et al. (US 6,303,139), each already of record, for the reasons set forth at page 7 of the office action dated March 26, 2008, and pages 6-7 of the office action dated January 22, 2009, of which reasons are herein incorporated by reference, in further view of Delack et al. (US 2003/0113309 A1).

Claims 1-2, and 7 were previous rejected over Atlas et al. in view of Passi et al. Applicant has amended the claims to limit them to a method of treating multiple sclerosis by administering N-acetyl cysteine amide (compound J) or the N-acetyl

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cysteine ethyl ester (compound A). As discussed in the previous office actions cited above, Atlas et al. teaches compound J for treating oxidative stress (page 7, lines 25-35). Passi et al. teaches that oxidative stress is significantly involved in the pathogenesis of multiple sclerosis (abstract, and column 1, lines 55-65). Additionally, Delack et al. teaches that multiple sclerosis (MS) patients have iron deposits and these high iron levels increase oxidative stress which is also increased by high levels of fatty acids also characteristic of MS patients and that this results in an antioxidant deficiency (page 10, [0090]). It would have been obvious to one of ordinary skill in the art at the time of the invention that compound J which is known to treat oxidative stress (as taught by Atlas et al.) would be useful for treating MS patients because of their high levels of oxidative stress as taught by both Passi and Delack et al.

Applicant has traversed the obviousness rejection over Atlas et al. in view of Passi et al. made in the final rejection mailed January 22, 2009 under the grounds that the mere suggestion of reducing oxidative stress is not enough to render the claims obvious. Applicant has also argued that because few antioxidant compounds are currently known to treat multiple sclerosis that one of skill in the art would not expect a compound known to treat oxidative stress to treat multiple sclerosis despite the fact that it is known that oxidative stress plays a role in multiple sclerosis. The examiner believes that the previous rejection still applies to the claims but has added the Delack reference to further strengthen the fact that oxidative stress is involved in multiple sclerosis and Delack et al. even indicates an antioxidant deficiency in MS patients which would lead

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one of skill in the art at the time of the invention to believe that an antioxidant which can treat oxidative stress would be useful in the treatment of multiple sclerosis.

Applicant also cited the fact that antioxidants vitamins C and E were thought to be useful for treating MS and a study by Zhang et al. which concluded that Vitamin C and E were not effective at reducing the risk (aka preventing) Multiple sclerosis as evidence that this was wrong. Firstly, the fact that vitamin C and E do not *prevent* multiple sclerosis actually provides almost no information on the ability of Vitamins C and E to *treat* multiple sclerosis. Treatment of an existing disease is different from preventing one from developing and one of ordinary skill in the art would not look to the study of Zhang et al. and conclude that vitamins C and E cannot be used to treat multiple sclerosis patients. Furthermore, just because not many antioxidants are known to treat multiple sclerosis is by no means an indicator that one cannot be used to treat multiple sclerosis.

Applicant has also argued that the previous action took the position "in the light of that (example 11) it appears that the applicant is enabled for treatment of MS with compound J" but that it was not without data such as that in example 11. There is a big difference between a drug having a reported effect (on oxidative stress) and that mechanism playing a role in a disease versus claims to a multitude of compounds that no activity has been shown at all. Data is not necessarily required to establish enablement, however in the instant application the compounds beyond compound J had no indication of any activity and thus one of skill in the art would just have an invitation to begin experimenting on the other compounds for possible active ones. The

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references of Atlas et al. and Passi et al. are limited, with Atlas et al. talking about a specific compound's activity at reducing oxidative stress and both Passi and Delack et al. teach that oxidative stress is involved in multiple sclerosis. One of ordinary skill in the art would have a clear motivation to use the compound J from Atlas et al. to treat multiple sclerosis based on the teachings of Atlas, Passi, and Delack et al. and there is a reasonable expectation of success because the compound is known to treat oxidative stress. Thus claims 1-2, 7 and 10 are unpatentable over Atlas et al. in view of Passi et al. in further view of Delack et al.

In response to applicant's remarks that antioxidants are not known in the art to treat multiple sclerosis, Malfroy-Camine et al. (US 6,589,948) is cited to show an additional antioxidant compound that was indicated for treatment of multiple sclerosis (column 4, lines 26-46).

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/
Examiner, Art Unit 1614